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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/821,718	SCHULTZ, CLYDE L.	
	Examiner	Art Unit	
	SARAH AL-AWADI	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03/19/2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 21-25* is/are pending in the application.

4a) Of the above claim(s) *4,15-19 and 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5-14, 21-23 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/27/2008 and 11/28/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's amendments and remarks filed 03/19/2009 and 10/14/2008. The Examiner acknowledges the following:

Claims 1 and 4 have been amended. Claim 1 includes the limitation wherein the drug comprises a steroid, and the disease being treated is neovascularization in the posterior segment. Claim 4 recites the drugs such as prednisolone, prednisone and hydrocortisone.

Claims 21-25 have been added.

Claims 1-14 and 21-25 are currently pending.

No new matter has been added with the claims, however Applicant's are reminded of the restriction election sent out in the Office Correspondence dated 08/03/2007. Applicant's elected the invention to include the species of VEGF antagonists, a hydrogel comprising a tetrapolymer of hydroxymethylmethacrylate, ethylene glycol, dimethylmethacrylate, and methacrylic acid, and neovascularization as the type of posterior segment disease for examination.

The general policy of the Office is not to permit the applicant to shift to claiming another invention after an election is once made and action given on the elected subject matter. Note that the applicant cannot, as a matter of right, file a request for continued examination (RCE) to obtain continued examination on the basis of claims that are independent and distinct from the claims previously claimed and examined (i.e., applicant cannot switch inventions by way of an RCE as a matter of right). When claims are presented which the examiner holds are drawn to an invention other than the one elected, he or she should treat the claims as outlined in MPEP § 821.03

Therefore as Applicant's have elected VEG F antagonists, claims 4 and 24 are withdrawn form consideration.

INFORMATION DISCLOSURE STATEMENT

The Information Disclosure Statements (IDS) received 06/27/2008 and 11/28/2008 have been acknowledged.

WITHDRAWN REJECTIONS

Rejections under 35 U.S.C. 102(b)

Claims 1-3, 5-6 and 9-11 were rejected under 35 USC 102(b) as being anticipated by Schultz et al., U.S. Patent 5,723,131. Applicant's amendment to claim 1 which includes steroids renders said rejection moot. Therefore said rejection is hereby **withdrawn**.

Claims 1-14 and 20 were rejected under 35 U.S.C. 102(b) as being anticipated by Schultz et al. United States Patent Application 2002/0197300 and evidenced by Osborne et al., Brain Research 751 (1997) 113-123. Applicant's amendment to claim 1 which includes steroids renders said rejection moot. Therefore said rejection is hereby **withdrawn.**

Rejection Under Nonstatutory Double Patenting

Claims 1-14 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 8, 11, 12, 13, 14, 15 of copending Application No. 10/132843 in view of SCHULTZ (US 6,410,045). The basis for this rejection

can be found in the previous office action dated 10/26/2007. The Application went abandoned 10/10/2008, therefore said rejection is hereby **withdrawn**.

MAINTAINED REJECTIONS

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-14, 21-23 and 25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of copending **Application No. 10/971,997.** Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed toward a polymeric hydrogel comprising

a drug such as a steroid wherein the drug is capable of treating posterior segment disease. The drug can be a number of agents such as steroids and VEGF antagonists. The hydrogel has a water content of between 10% and 90% or between 37.5% and 75% and is composed of a tetrapolymer of hydroxymethylmethacrylate, ethylene glycol, dimethacrylate, and methacrylic acid. The hydrogel can be a contact lens capable of correcting vision in the range of +8.0 to -8.0 diopters and has a base curve of 8.0 and 9.0. The drug is further capable of being passively delivered to the posterior segment of the eye or ocular environment.

The '997 claims are similar in that the treatment consists of an anti-angiogenesis compound. Furthermore, instant claim 20 specifically states the drug can be an angiogenesis inhibitor and VEGF antagonist. Additionally, tamoxifen, thalidomide and VEGF antibodies are stated as the drugs in both applications. The '997 also discloses steroid molecules such as tetrahydrocortisol-S as the types of drugs used with the hydrogel.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to make a polymeric hydrogel for the treatment of posterior segment disease because '997 teaches the use of the same hydrogel and the same drugs.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-14, 21-23 and 25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 13-20 of **U.S. Patent No. 7,169,406.** Although the conflicting claims are not identical, they are not patentably distinct from each other because the '406 application claims differ from the instant claims (described above) whereby an

anti-inflammatory compound is required in claim 1. The compound can be dexamethasone, fluormetholone, rimexolone or prednisolone. The type of anti-inflammatory compound used such as prednisolone is also a steroid, therefore, the same hydrogel with the steroid drugs are taught in both the instant claims and the '406 claims.

Claims 1-14 **remain** provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 30-34, 38-39, 47, 58 and 60-80 of copending **Application No. 11/102454** in view of Schultz (US 6,410,045). The basis for this rejection can be found in the previous office action dated 10/26/2007. Schultz, et al. teaches that corticosteroid delivered through polymer hydrogels are well known in the art, thus it would have been obvious to the skilled artisan to deliver a steroid in the hydrogel taught by Schultz. Furthermore, claims 21-23 and 25 are rejected for the same reasons made of record in the prior office action dated 10/26/2007 as Applicants have added VEGF antagonists to the hydrogel. The diseases listed in claims 21 and 25 are an intended use of the polymer systems recited by Scultz.

RESPONSE TO REMARKS

It is noted that Applicants have filed Terminal Disclaimers for patent 7,169,406 and 11/102,454. The Terminal Disclaimers filed 03/19/2009 have **not** been approved because the owner on the Terminal Disclaimer does not match with the assignment.

Application Number 10/971,997 remains rejected as Applicants have not filed a response or a Terminal Disclaimer. Applicants are respectfully reminded that in order to be considered fully responsive to this office action, a response on behalf of this rejection **must** be submitted.

Failure to submit such a response will result in the mailing of a Notice of Non-Responsiveness from the Office.

NEW REJECTIONS

In light of Applicant's amendments, most notably to claims 1, as well as the newly added claims, the following rejections have been newly added:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 22-23 recited the broad genus claim VEGF antagonist. This does not have

sufficient description in the specification, nor are a representative number of types of VEGF antagonist compounds described to demonstrate that applicant was in possession at the time of filing.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus …") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163. While all of the factors have been considered, a sufficient amount for a *prima facie* case are discussed below.

In the instant case, the claims are drawn to polymeric hydrogels which comprise a VEGF antagonist.

(1) Level of skill and knowledge in the art:

The level of skill and knowledge in the art is high.

(2) Partial structure:

It is not clearly described nor are any examples provided in the specification for types of VEGF antagonists.

(3) Physical and/or chemical properties and (4) Functional characteristics:

Applicants disclose that the polymeric hydrogels contain a VEGF antagonist. It is not clearly described what types of molecules are defined as VEGF antagonists.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claim(s) 22-23 are generic to a VEGF antagonist. The claims lack written description because there is no disclosure or examples of the types of VEGF antagonists. The specification does not provide sufficient descriptive support for the compounds embraced by the claims with reference to VEGF antagonists.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outline[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, and 6-13, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Guy Fortier, United States Patent 5,733,563.

Claim 1 recites a polymeric hydrogel comprising a drug for the treatment of a posterior segment disease, wherein said drug comprises a steroid and is capable of being passively released from the polymeric hydrogel while positioned on the eye in a therapeutically effective amount to ameliorate and/or stabilize neovascularization in the posterior segment.

Fortier teaches the use of polymer hydrogels (PEG) which comprise drugs such as hydrocortisone and prednisone. (column 9, lines 28-55 also refer to figure 4) Such polymer hydrogels are useful for making contact lenses or devices for controlled drug release.(column 3, lines 25-31) Regarding the limitations wherein the drug is used for the treatment of a posterior segment disease, the Examiner interprets said limitation as reciting an intended use. Regarding the limitation wherein the drug is capable of being passively released from the polymeric hydrogel while positioned on the eye in a therapeutically effective amount to ameliorate and/or stabilize neovascularization in the posterior segment; until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner as a property and is directed toward the polymeric hydrogel which is instantly claimed.

Regarding claim 6 which recites wherein said drug is capable of being passively released into an ocular environment under ambient conditions, claim 7 which recites wherein said drug is

capable of being delivered to the posterior segment of the eye, and claim 8 wherein said drug is capable of being delivered to the macula or retina, the Examiner interprets said limitations as being an intended use of the composition.

Regarding claim 9 which recites wherein said drug is capable of being passively released into an ocular environment under existing conditions; until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed toward the polymeric hydrogel which is instantly claimed.

Claim 10 recites the hydrogel of claim 1, wherein the hydrogel is shaped as a contact lens. Fortier teaches that the hydrogels of the invention are useful for making contact lenses or devices for controlled drug release. (column 3, lines 25-31)

Regarding the limitation of claim 11 which recites the hydrogel of claim 10, wherein said hydrogel is capable of correcting vision, claim 12 which recites the hydrogel of claim 11 wherein said hydrogel is capable of correcting vision in the range of +8.0 to -8.0 diopters, and claim 13 which recites the hydrogel of claim 10 wherein said hydrogel has a base curve between 8.0 and 9.0; until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed toward the polymeric hydrogel which is instantly claimed.

Claim 21 recites the hydrogel of claim 1, wherein the posterior segment disease is selected from the group consisting of diabetic retinopathy, macular degeneration, macular edema, and vascular retinopathy. This limitation further limits the intended use of the composition as recited in claim 1, and is therefore directed towards an indented use of the composition.

Claims 1, 6-14, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Bawa, United States Patent 4, 668, 506.

Claim 1 recites a polymeric hydrogel comprising a drug for the treatment of a posterior segment disease, wherein said drug comprises a steroid and is capable of being passively released from the polymeric hydrogel while positioned on the eye in a therapeutically effective amount to ameliorate and/or stabilize neovascularization in the posterior segment.

Bawa teaches the use of polymer hydrogels to deliver therapeutic agents. (abstract) The invention slowly dispenses a drug into the eye. (see column 1, line 5). The hydrogels deliver agents such as steroids. (see claim 5) Furthermore the dosage form can be delivered through the use of contact lens. (claim 9) Regarding the limitations wherein the drug is used for the treatment of a posterior segment disease, the Examiner interprets said limitation as an intended use of the composition. Regarding the limitation wherein the drug is capable of being passively released from the polymeric hydrogel while positioned on the eye in a therapeutically effective amount to ameliorate and/or stabilize neovascularization in the posterior segment; until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner as a property and is directed toward the polymeric hydrogel which is instantly claimed.

Regarding claim 6 which recites wherein said drug is capable of being passively released into an ocular environment under ambient conditions, claim 7 which recites wherein said drug is

capable of being delivered to the posterior segment of the eye, and claim 8 wherein said drug is capable of being delivered to the macula or retina, the Examiner interprets said limitations as being an intended use of the composition.

Regarding claim 9 which recites wherein said drug is capable of being passively released into an ocular environment under existing conditions; until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed toward the polymeric hydrogel which is instantly claimed.

Claim 10 recites the hydrogel of claim 1, wherein the hydrogel is shaped as a contact lens. As stated above, Bawa teaches polymeric hydrogels which are contact lenses. (claims 1 and 9)

Regarding the limitation of claim 11 which recites the hydrogel of claim 10, wherein said hydrogel is capable of correcting vision, claim 12 which recites the hydrogel of claim 11 wherein said hydrogel is capable of correcting vision in the range of +8.0 to -8.0 diopters, and claim 13 which recites the hydrogel of claim 10 wherein said hydrogel has a base curve between 8.0 and 9.0; until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed toward the polymeric hydrogel which is instantly claimed.

Claim 14 recites the hydrogel of claim 1, wherein said hydrogel comprises and ionic polymer. Bawa teaches the use of ionic polymer contact lens which comprises hydroxyethyl methacrylate vinyl pyrrolidone with methacrylic acid. (see figure 4)

Claim 21 recites the hydrogel of claim 1, wherein the posterior segment disease is selected from the group consisting of diabetic retinopathy, macular degeneration, macular

edema, and vascular retinopathy. This limitation further limits the intended use of the composition as recited in claim 1, and is therefore directed towards an indented use of the composition.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz et al. United States Patent Application 2002/0197300 and Schwartz, United States Patent 5,212,168.

Claim 1 recites a polymeric hydrogel comprising a drug for the treatment of a posterior segment disease, wherein said drug comprises a steroid and is capable of being passively released from the polymeric hydrogel while positioned on the eye in a therapeutically effective amount to ameliorate and/or stabilize neovascularization in the posterior segment.

Schultz et al. teaches polymeric hydrogel contact lenses wherein the lenses gradually release medication. (abstract and paragraph 0014) The limitation wherein the hydrogel comprises a drug for the "treatment of a posterior segment disease is interpreted by the Examiner as an intended use of the composition. Schultz et al. expressly teaches the use of hydrogels to release drugs to the eye. Schultz further teaches that it is known to deliver such anti-glaucomatous medications in combination with corticosteroid medications and discloses U.S. Patent 5,212,168 which exemplifies that using polymeric hydrogel contact lenses to deliver anti-glaucomatous medications in combination with corticosteroid medications is well known in the art. The corticosteroid medications of U.S. Patent 5,212,168 include that of prednisolone, prednisone, and hydrocortisone which can be delivered through a polymeric hydrogel. Regarding the limitations wherein the drug is used for the treatment of a posterior segment disease, the Examiner interprets said limitation as reciting an intended use. Regarding the limitation wherein the drug is capable of being passively released from the polymeric hydrogel while positioned on the eye in a therapeutically effective amount to ameliorate and/or stabilize neovascularization in the posterior segment; until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner as a property and is directed toward the polymeric hydrogel which is instantly claimed.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to form polymeric hydrogels as taught by Schultz et al., wherein such hydrogels comprise steroids to ameliorate and/or stabilize neovascularization because Schultz et al. suggests that it is known in the art to incorporate corticosteroids into hydrogels.

Claims 2-3, 5-14, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz et al. United States Patent Application 2002/0197300 with respect to claim 1 as presented above.

Claim 3 recites the polymeric hydrogel of claim 1, wherein the hydrogel has a water content of between 10% and 90%, and claim 3 recites the polymeric hydrogel of claim 2, wherein said hydrogel has a water content between 37.5% and 75%. Schultz et al. teaches that the polymeric hydrogels contain a water content between 10-90%, which falls within the instantly claimed range. Furthermore as it is obvious to the skilled artisan that hydrogels contain water, it would have been within the purview of one of ordinary skill in the art to optimize the water content ratio as MPEP 2144.05 recites "where the general conditions in the claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."

Claim 5 recites the hydrogel of claim 1, wherein said hydrogel comprises a tetrapolymer of hydroxymethylmethacrylate, ethylene glycol, dimethylmethacrylate, and methacrylic acid. Schultz et al. teaches a tetrapolymer hydrogel such as hydroxymethylmethacrylate, ethylene glycol, dimethylmethacrylate, and methacrylic acid. (paragraph 0020)

Regarding claim 6 which recites the hydrogel of claim 1, wherein said drug is capable of being passively released into an ocular environment under ambient conditions, absent evidence of criticality, until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed towards the polymer hydrogel which is instantly claimed.

Regarding claim 7 which recites the hydrogel of claim 1, wherein said drug is capable of being delivered to the posterior segment, and claim 8 which recites the drug is capable of being delivered to the macula or retina, absent evidence of criticality, until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed towards the polymer hydrogel which is instantly claimed.

Regarding claim 9 which recites the hydrogel of claim 1, wherein said drug is capable of being passively released into an ocular environment under existing conditions, absent evidence of criticality, until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed towards the polymer hydrogel which is instantly claimed.

Claim 10 recites the hydrogel of claim 1, wherein said hydrogel is shaped as a contact lens. Schultz et al. teaches polymeric hydrogel contact lenses. (abstract)

Regarding claim 11 which recites the hydrogel is capable of correcting vision, and claims 12-13 which recite the vision range as +8 to -8 diopters, wherein the hydrogel has a base curve between 8 and 9, absent evidence of criticality, until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed towards the polymer hydrogel which is instantly claimed.

Claim 14 recites the hydrogel of claim 1, wherein said hydrogel comprises an ionic polymer. Schultz et al. teaches that the polymer can be ionic. (paragraph 0031)

Claim 21 recites the hydrogel of claim 1, wherein the posterior segment disease is selected from the group consisting of diabetic retinopathy, macular degeneration, macular edema, and vascular retinopathy. This limitation further limits the intended use of the

composition as recited in claim 1, and is therefore directed towards an indented use of the composition.

It would have been prima facie obvious to one of ordinary skill in the art to create a polymer hydrogel which comprises steroids identical to that which is instantly claimed because Shultz et al. suggests that it is well known in the art to incorporate steroids into polymer hydrogel contact lenses. Thus, it would have been obvious to the skilled artisan to incorporate steroids into the specific polymer hydrogels as taught by Schutlz.

Claims 1-3, 6-13 and 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. United States Patent Application 2004/0071761 in view of Wikipedia. (hydrogel article, please see 892 form)

Claim 1 recites a polymeric hydrogel comprising a drug for the treatment of a posterior segment disease, wherein said drug comprises a steroid and is capable of being passively released from the polymeric hydrogel while positioned on the eye in a therapeutically effective amount to ameliorate and/or stabilize neovascularization in the posterior segment.

Miller et al. teaches pharmaceutical compounds for the treatment of posterior retinal conditions of the eye. (paragraph 0028) The invention comprises a drug which is impregnated into a hydrogel. (paragraph 0073) It is well known in the art that hydrogels comprise water and polymers. (see wikipedia article) Miller further teaches that drugs such as VEGF antagonists or steroids can be present as the drug. (paragraphs 0029 and 0059) Regarding the limitation "for the treatment of a posterior disease", the Examiner interprets said limitation as an intended use of the

composition. Furthermore, regarding the limitation wherein the steroid is capable of being passively released from the polymeric hydrogel and wherein the drug ameliorates and/or stabilizes neovascularization in the posterior segment; until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed toward the polymeric hydrogel which is instantly claimed.

Regarding the limitation of claim 2 which recites the polymeric hydrogel of claim 1, wherein the hydrogel has a water content of between 10% and 90%, and claim 3 which recites the polymeric hydrogel of claim 2, wherein said hydrogel has a water content between 37.5% and 75%, as it is well known to the skilled artisan that hydrogels comprise water, it would have been within the purview of the skilled artisan to optimize the water ratio of such hydrogels. Furthermore, MPEP 2144.05 recites "where the general conditions in the claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."

Regarding claim 6 which recites the hydrogel of claim 1, wherein said drug is capable of being passively released into an ocular environment under ambient conditions; absent evidence of criticality, until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed towards the polymer hydrogel which is instantly claimed.

Regarding claim 7 which recites the hydrogel of claim 1, wherein said drug is capable of being delivered to the posterior segment, and claim 8 which recites the drug is capable of being delivered to the macula or retina, the Examiner interprets said limitation as reciting and intended

use. Furthermore, Miller et al. teaches treating macular degeneration and disorders such as glioblastomas which affect all parts of the eye. (paragraph 0058)

Regarding claim 9 which recites the hydrogel of claim 1, wherein said drug is capable of being passively released into an ocular environment under existing conditions, absent evidence of criticality, until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed towards the polymer hydrogel which is instantly claimed.

Claim 21 recites the hydrogel of claim 1, wherein the posterior segment disease is selected from the group consisting of diabetic retinopathy, macular degeneration, macular edema, and vascular retinopathy. This limitation further limits the intended use of the composition as recited in claim 1, and is therefore directed towards an indented use of the composition.

Claim 22 recites a polymeric hydrogel comprising a drug for the treatment of a posterior segment disease, wherein said drug comprises an angiogenesis inhibitor and is capable of being passively released from the polymeric hydrogel while positioned on the eye in a therapeutically effective amount to ameliorate and/or stabilize neovascularization in the posterior segment, and claim 23 lists that the drug can be selected to be that of a VEGF antagonist. Miller et al. teaches pharmaceutical compounds for the treatment of posterior retinal conditions of the eye. (paragraph 0028) The invention can comprise a drug which is impregnated into a hydrogel. (paragraph 0073) It is well known in the art that hydrogels comprise water and polymers. (see wikipedia article) Miller further teaches that drugs such as VEGF antagonists (angiogenesis inhibitor) or steroids can be present as the drug. (paragraphs 0029 and 0059) Regarding the

limitation "for the treatment of a posterior disease" and wherein the drug ameliorates and/or stabilizes neovascularization in the posterior segment, the Examiner interprets said limitation as an intended use of the composition. Furthermore, regarding the limitation wherein the angiogenesis inhibitor is "capable of being passively released from the polymeric hydrogel; until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed toward the polymeric hydrogel which is instantly claimed.

Claim 25 recites the hydrogel of claim 22 wherein the posterior segment disease is selected from the group consisting of diabetic retinopathy, macular degeneration, macular edema, and vascular retinopathy. This limitation further limits the intended use of the composition as recited in claim 22, and is therefore directed towards an indented use of the composition.

It would have been prima facie obvious to one of ordinary skill in the art to create polymer hydrogel systems for the eye which comprise VEG F antagonists or steroids because Miller et al. suggests combining the drugs with polymer hydrogels for the treatment of various ocular conditions.

Claims 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sponsel et al. United States Patent Application 2004/0198829.

Claim 22 recites a polymeric hydrogel comprising a drug for the treatment of a posterior segment disease, wherein said drug comprises an angiogenesis inhibitor and is capable of being

passively released from the polymeric hydrogel while positioned on the eye in a therapeutically effective amount to ameliorate and/or stabilize neovascularization in the posterior segment, and claim 23 lists that the drug can be selected to be that of a VEGF antagonist.

Sponsel et al. teaches matrices of solid hydrophobic polymers wherein such matrices include hydrogels. (paragraph 0221) The therapeutic agents of the invention are delivered to the eye. (paragraph 0009) Sponsel et al. teaches the use of an angiogenesis inhibitor such as VEGF antagonists as one type of drug that can be delivered the eye. (paragraph 0172-0173) The diseases that can be treated with the invention of Sponsel can include that of neovascularization. (paragraph 0079) The limitations wherein the inhibitor is "capable of being passively released from the polymeric hydrogel in a therapeutically effective amount to ameliorate and/or stabilize neovascularization in the posterior segment is interpreted by the Examiner as an intended use of the composition.

Claim 25 recites the hydrogel of claim 22, wherein the posterior segment disease is selected from the group consisting of diabetic retinopathy, macular degeneration, macular edema, and vascular retinopathy. This limitation further limits the intended use of the composition as recited in claim 1, and is therefore directed towards an indented use of the composition.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to create polymer hydrogels for delivery to the eye comprising angiogenesis inhibitors such as VEGF because Sponsel et al. suggests the delivery of such hydrogel systems to the eye and teaches VEGF antagonists as a drug that can be included.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah Al-Awadi whose telephone number is (571) 270-7678. The examiner can normally be reached on 9:30 am - 6:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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